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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,683	09/26/2003	Chi-Hung Lin	9751.106USU1	9244
23552	7590	11/23/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 11/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,683	LIN ET AL.	
	Examiner	Art Unit	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,8,10,11 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-26 is/are allowed.
- 6) ☒ Claim(s) 1,3,8,10,11,17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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CLAIMS 1, 3, 8, 10, 11 AND 17-26 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment filed October 22, 2004 has been received and entered into the application. Accordingly, claims 1, 3, 8 and 10 and the Title have been amended; claims 2, 4-7, 9 and 12-16 have been canceled; and claims 17-26 have been added.

In light of the above amendments, the claim objection and rejections under 35 U.S.C. §§ 112, first paragraph and 102 set forth in the previous Office action dated June 24, 2004 are withdrawn.

Pending Claims

The present claims are directed to the treatment of breast, hepatocellular and cervical cancer which involves the administration of abietic acid or derivatives thereof. Claim 1 is representative of the claimed subject matter and reads:

1. (currently amended) A method for inhibiting the growth of a cancer cell, ~~a cervical carcinoma cell, a hepatocellular carcinoma cell, or a breast cancer cell~~, comprising treating the cancer cell with administering an effective amount of abietic acid or derivatives thereof ~~to the cell~~.

Claims 3, 8, 10, 11, 17 and 18 further relate to claim 1 and are directed to the specific host of the method, the effect of the active agent on the tumor cell and to the alleviation of symptoms of the recited cancers.

Claims 19-26 are directed to enhancing the inhibitory effect of an anticancer agent.

Claim 19 is representative thereof and reads:

19. (new) A method for enhancing the inhibitory activity of an anticancer drug in cervical carcinoma cells, hepatocellular carcinoma cells, or breast cancer cells, comprising administering to the cells abietic acid or derivative thereof in combination with the anticancer drug.

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Claims 20-26 depend from claim 19 and are directed to the mode of administration, host and the identity of the anticancer drug.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 8, 10, 11, 17 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Saxena et al. (U.S. Patent Application Publication No. 2003/0092674, newly cited by the Examiner).

Saxena et al. teach the administration, which may be oral (page 9, section [0080], line 8), of a composition which comprises one or more abietic acid derivatives (page 3, sections [0019], [0020], [0022] and [0023]; page 4, sections [0026] and [0027]; and pages 10+ at claim 1) and a pharmaceutically acceptable carrier for the cancers including breast, cervix, i.e., cervical and liver, i.e., hepatic which would necessarily include hepatocellular (see page 17, claim 7 at lines 15, 18, 20 and 21 thereof).

The requirement of claims 17 and 18 are not disclosed, i.e., “human”. However, the reference discloses “individual” (page 9, section [0076]), “subject” (page 9, section [0078]) and “mammal” (page 10, claim 1 at line 3 thereof) and such is deemed to represent a genus of hosts

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of sufficient size and nature that a human host would be placed within the possession of the public, i.e., anticipated, by the disclosure of Saxena et al.

Also, while not expressly disclosed, the requirements of claims 3 and 10 regarding the reaction of the tumor or cancer cells are deemed inherently disclosed in the reference because the same drugs are being administered to the same host not distinct from those claimed.

To anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber*, 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 8, 10, 11, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saxena et al., as above, in view of Bang et al. (U.S. Patent No., 5,248,696), already of record.

The difference between the above and the claimed subject matter lies in that Saxena et al. fails to disclose that abietic acid itself would be as effective as the abietic acid derivatives.

However, to the skilled artisan, the claimed subject matter would have been obvious because Bang et al. disclose that abietic acid itself is effective for various cancer types including sarcoma, lung, melanoma, ovarian and renal (see the abstract, col. 1, line 55 – col. 3, line 7, col. 3, lines 30-32 and col. 7, lines 12-32 and lines 44-52).

The skilled artisan would have been motivated to administer abietic acid for the purposes taught by Saxena et al., i.e., the treatment of the same cancer types (breast, hepatocellular and cervical) presently claimed, based not only on the clear structural similarities of the abietic acid derivatives of Saxena et al. to abietic acid itself, i.e., the structural similarity would have imbued the skilled artisan with at least a reasonable expectation that similar activity would be present, but also because Saxena et al. disclose that the abietic acid derivatives are effective for treating those same cancer types disclosed by Bang for abietic acid itself, i.e., sarcoma, lung, melanoma, ovarian and renal (see Saxena et al. at page 17, claim 1 at lines 28 “sarcoma”, 16 “lung”, 27

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"melanoma" and 20 "kidney"). That is, having before him/her the disclosures of both Saxena et al. and Bang et al., for the reasons above, the skilled artisan would have had at least a reasonable expectation that abietic acid taught by Bang et al. would have therapeutic activities similar to the abietic acid derivatives taught by Saxena et al. and thus would have expected that abietic acid to be effective for the presently claimed cancer types, i.e., breast, hepatocellular and cervical.

Accordingly, for the above reasons, claims 1, 3, 8, 10, 11, 17 and 18 are deemed properly rejected.

Allowable Subject Matter

Claims 19-26 are in condition for allowance because the references of record fail to teach or suggest the presently claimed method for enhancing the inhibitory activity of an anticancer drug.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

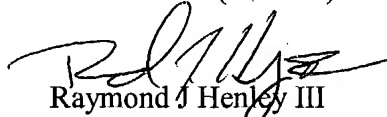
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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

November 21, 2004